

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AVADEL CNS PHARMACEUTICALS, LLC.

Defendant.

C.A. No. 21-691-GBW

JAZZ PHARMACEUTICALS, INC., *et al.*,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS, LLC.

Defendant.

C.A. No. 21-1138-GBW

JAZZ PHARMACEUTICALS, INC., *et al.*,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS, LLC.

Defendant.

C.A. No. 21-1594-GBW

**LETTER FROM DANIEL M. SILVER, ESQ. TO THE  
HONORABLE GREGORY B. WILLIAMS IN OPPOSITION TO JAZZ'S REQUEST TO  
STAY EXPERT DISCOVERY RELATED TO THE '963 PATENT**

Dear Judge Williams:

This firm, along with Latham & Watkins LLP and Durie Tangri LLP, represents Defendant Avadel CNS Pharmaceuticals LLC (“Avadel”). We respectfully ask that the Court deny Jazz’s request to stay expert discovery related to Jazz’s U.S. Patent No. 8,731,963 (the “REMS System Patent”) (D.I. 276). In its request, Jazz takes the extraordinary position that it is entitled to maintain its infringement claims regarding the REMS System Patent to continue excluding Avadel from the market, while openly admitting that it does not intend to present those allegations to the Court—*now or ever*—or even attempt to substantiate them with expert evidence.

Jazz’s request to stay expert discovery is merely the latest episode in Jazz’s years-long, contrived effort to leverage the REMS System Patent into triggering the Hatch-Waxman regulatory scheme, thereby keeping Avadel’s once-nightly narcolepsy treatment off the market for as long as possible. As this Court is aware, Jazz improperly listed the REMS System Patent in the Orange Book along with an inaccurate use code. Based on those actions, the FDA required Avadel to certify to the REMS System Patent. (D.I. 231 at 2.) Jazz thereafter sued Avadel, which triggered a statutory stay preventing the FDA from approving Avadel’s NDA. (*Id.*) While the Court issued an order requiring Jazz to remove the REMS System Patent from the Orange Book, that order is stayed pending Jazz’s appeal. (D.I. 265.) The REMS System Patent must be removed as an impediment before the “FDA can take further action on Avadel’s application.” (D.I. 276 at 1).

Following this Court’s ruling, but before the Federal Circuit stayed the delisting order, Avadel proposed that Jazz drop its infringement allegations regarding the REMS System Patent because it expired December 17, 2022 and any additional regulatory exclusivity was predicated on its improper Orange Book listing. (D.I. 276, Ex. A.) Jazz refused, instead proposing the stay of expert discovery that is the subject of this motion. (D.I. 276, Ex. B at 3.) Avadel opposed, recognizing that Jazz’s proposed stay during the pendency of the appeal would only serve to reward Jazz’s gamesmanship and help it run out the clock. The regulatory exclusivity period for the REMS System Patent ends June 17, 2023. (D.I. 276 at 2.) Oral argument in the appeal is not scheduled until February 14, 2023, and the Federal Circuit may take additional time to issue its ultimate decision. *Jazz Pharm., Inc. v. Avadel CNS Pharm. LLC*, No. 23-1186, D.I. 16 at 1 (Fed. Cir. Dec. 5, 2022). Thus, if the Court stays expert discovery, the parties would not have time to restart it after the appeal. Jazz would have received the benefit of its entire exclusivity period—a period based solely on the same Orange Book listing this Court already decided was improper—without even having to attempt to substantiate its infringement allegations with any expert opinion.

Jazz did not make the required showing in its letter brief. Delaware courts consider three factors in deciding whether to grant a stay: “(1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party.” *See Am. Axle &*

*Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168-LPS, 2021 WL 616992, at \*2 (D. Del. Feb. 17, 2021). Here, all three weigh against staying expert discovery

**Factor 1: A Stay Will Not Simplify the Issues for Trial, as Jazz has Admitted It Does Not Intend to Try the REMS System Patent**

A stay will not simplify the issues for trial, as Jazz does not intend to try the REMS System Patent regardless of the outcome of its appeal. As Jazz explained, the REMS System Patent “expired on December 17, 2022. The regulatory exclusivity associated with the [REMS System Patent] cannot extend beyond June 17, 2023. And so, by the time the expert discovery period closes, there will be no need to resolve infringement or validity of the [REMS System Patent] from either a patent or regulatory law perspective.” (D.I. 276 at 2.) Thus, Jazz has admitted that its infringement allegations will not be presented at trial, regardless of the appeal’s outcome.

To the extent Jazz argues that a stay of discovery on the REMS System Patent would simplify expert discovery, Avadel’s proposal that Jazz dismiss its claims now that both parties recognize them as moot would accomplish the same effect. Such a step would also be more appropriate than delaying discovery in view of both Jazz’s admission that it does not intend to try the claims regardless of the outcome of its appeal and Jazz’s statutory obligation to “reasonably cooperate in expediting” actions brought under the Hatch-Waxman Act. 21 U.S.C. § 355(c)(3)(C)

Additionally, Jazz’s basis for alleging infringement is relevant, even if the REMS System Patent will never make it to trial. Avadel has requested fees under 35 U.S.C. § 285 based on Jazz’s exceptional litigation conduct. (D.I. 11 at 50.) Weak or baseless infringement positions can form the basis for such a fee award. *Innovation Sciences, LLC v. Amazon.com, Inc.*, 842 Fed. App’x 555, (Fed. Cir. 2021) (awarding fees based on “litigation positions [that] were so substantively weak after the claim construction occurred that this case stands out from others.”). Further, Avadel has brought antitrust counterclaims predicated on Jazz’s ongoing exclusion of Avadel from the market. *Jazz Pharm., Inc. v. Avadel CNS Pharm. LLC*, C.A. No. 22-941-GBW, D.I. 14 at 41-49 (D. Del. Oct. 21, 2022). Therefore, even if Jazz has no intention of actually trying its case, Jazz will still have to substantiate its infringement allegations with expert opinion. It would be most efficient to conduct that discovery now, consistent with the scheduling order.

**Factors 2 & 3: Given the Case’s Status, A Stay Gives Jazz a Clear Tactical Advantage, Leaving Its Regulatory Exclusivity Intact, Without a Resolution on the Merits<sup>1</sup>**

The second and third factors also weigh against a stay because the current status of the case means staying expert discovery on the REMS System Patent provides a clear tactical advantage to Jazz. While expert discovery will not close before Jazz’s regulatory exclusivity expires, under the current schedule, Jazz must disclose the scope of its experts’ infringement opinions by January 17<sup>th</sup>. (D.I. 240.) This matters because Jazz does not have a viable infringement case regarding the REMS System Patent. Specifically, Jazz did not prevail on a single claim construction argument with respect to the REMS System Patent (D.I. 229 at 14-20) and failed to offer any infringement

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<sup>1</sup> While the regulatory exclusivity is triggered by Jazz’s second-filed action on the REMS System Patent, Jazz’s inability to maintain its claims in this case would result in the termination of that action and the associated regulatory exclusivity.

contentions under Avadel's proposed constructions. (Exhibit 1, Jazz's Final Infringement Contentions at 1-42.)

Given the foregoing, Avadel understands that Jazz has no cognizable basis for asserting infringement, which presumably is the real reason for Jazz's request. A stay would allow Jazz to avoid reckoning with the consequences of its claim construction losses and deficient infringement allegations. Jazz's inability to present any credible expert opinion on the issue ultimately would be relevant to a variety of issues, including the aforementioned request for fees and antitrust counterclaims, as well as whether Avadel could pursue summary judgment based on Jazz's failure of proof or other deficiencies in the opinions.

Put simply, Jazz's proposed stay is a windfall for Jazz because it allows Jazz to maintain claims it cannot support without ever requiring Jazz to substantiate its allegations. If Jazz wishes to litigate its claims, it should litigate them. Otherwise, it should dismiss them based on the mootness it has already recognized.

Respectfully submitted,

*/s/ Daniel M. Silver*

Daniel M. Silver (#4758)

cc: Counsel of Record (via CM/ECF and E-Mail)

# EXHIBIT 1

THIS DOCUMENT HAS  
BEEN REDACTED IN ITS  
ENTIRETY

**CERTIFICATE OF SERVICE**

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on December 29, 2022 on the following counsel in the manner indicated below.

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Dated: December 29, 2022

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